

to bear a satisfactory statement of the active ingredients, and that of the laxative cold tablets and the hypodermic tablets also bore false and misleading statements. The epinephrine hypodermic tablets contained only three-fourths as much epinephrine as the amount declared on the label.

On April 30, May 8, August 29, and September 8, 1942, the United States attorneys for the Northern District of Illinois, Eastern District of Wisconsin, and the Northern and Southern Districts of Ohio filed libels against 49 bottles each containing 100, and 35 bottles each containing 1,000 laxative cold tablets at Chicago, Ill.; 14,800 Rx S368230 Pills at Oconomowoc, Wis.; 6,040 packages each containing 100 epinephrine tablets at Columbus, Ohio; and 2,045 tubes each containing 20 epinephrine tablets at Toledo, Ohio, alleging that the articles had been shipped in interstate commerce within the period from on or about January 13, 1941, to on or about July 14, 1942, by Parke, Davis & Co. from Detroit, Mich.; and charging that the cold tablets and pills were misbranded, and that the epinephrine tablets were adulterated and misbranded.

Analyses of samples showed that the laxative cold tablets each contained approximately 2 grains of acetanilid, plant extractives (including resinous material), a quinine compound, and caffeine; and that the pills contained aloin and an extract of cascara sagrada.

The laxative cold tablets were alleged to be misbranded: (1) In that the labeling failed to bear adequate directions for use since it contained no directions as to frequency or duration of administration. (2) In that the labeling failed to bear adequate warnings since (a) they contained acetanilid and it did not warn that frequent or continued use might therefore be dangerous, causing serious blood disturbances, anemia, collapse, or a dependence upon acetanilid, and that they should not be given to children; and (b) they contained laxative ingredients and the label did not warn against their use in case of abdominal pain and nausea, vomiting, or other symptoms of appendicitis; or that frequent or continued use might result in dependence upon laxatives to move the bowels. (3) In that the statement on the label, "Cold \* \* \* (Grip)," was false and misleading since they did not constitute an adequate treatment for cold or gripe.

The pills were alleged to be misbranded: (1) In that the labeling failed to bear any directions for their use. (2) In that the labeling failed to warn that they were not to be used in the presence of abdominal pain, nausea, vomiting, or other symptoms of appendicitis; and that frequent or continued use might result in dependence upon laxatives. (3) In that the label failed to bear the common or usual names of the active ingredients since "Cascarin Bitter" is not the common or usual name of any substance.

The epinephrine tablets were alleged to be adulterated in that their strength differed from that which they purported and were represented to possess, namely, (label) "Tablets Epinephrine 3/200 grain" and "One tablet dissolved in 1cc. of water makes a 0.1% solution," since each tablet contained less than 3/200 grain of epinephrine and 1 tablet dissolved in 1 cc. of water would make a solution of less concentration than 0.1 percent of epinephrine. They were alleged to be misbranded in that the above-quoted statements were false and misleading.

One June 1, August 26, and November 9, 1942, no claimant having appeared for the seizures at Chicago, Oconomowoc, and Columbus, judgments were entered ordering that they be destroyed. On February 6, 1943, Parke, Davis & Co., claimant for the seizure at Toledo, having admitted the material allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be brought into compliance with the law under the supervision of the Food and Drug Administration.

**762. Adulteration and misbranding of Gloria Tonic tablets. U. S. v. 74 Packages of Gloria Tonic. Default decree of condemnation and destruction. (F. D. C. No. 7338. Sample No. 80185-E.)**

On April 16, 1942, the United States attorney for the Northern District of Ohio filed a libel against 74 packages of Gloria Tonic tablets at Cleveland, Ohio, alleging that the article had been shipped in interstate commerce on or about October 20, 1941, by the John A. Smith Co. from Oconomowoc, Wis.; and charging that it was adulterated and misbranded.

Analysis showed that the tablets contained iron (0.77 grain), sodium salicylate (3.64 grains), colchicine (0.003 grain), and extract of cascara sagrada.

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely, "Each tablet contains reduced Iron 1 gr., \* \* \* Sodium Salicylate 5 gr., Colchicine 1-250 gr."

It was alleged to be misbranded: (1) In that the labeling failed to bear adequate directions for use since those which appeared on the label did not provide for sufficient medication to constitute a treatment for gout. (2) In that [its labeling failed to bear adequate warnings] since it was a laxative and the label failed to warn that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use might result in dependence upon laxatives. (3) In that the statement "Tonic \* \* \* An Allevial Treatment Useful in \* \* \* Gout" was false and misleading since the tablets when used as directed did not constitute a tonic or treatment for gout.

On June 26, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**763. Misbranding of solution of citrate of magnesia. U. S. v. 144 Bottles of Solution Citrate of Magnesia U. S. P. Default decree of condemnation and destruction. (F. D. C. No. 7397. Sample No. 79270-E.)**

On April 27, 1942, the United States attorney for the Southern District of Indiana filed a libel against the above-named product at Richmond, Ind., alleging that it had been shipped in interstate commerce on or about January 26, 1942, by Gordon Pharmacal Co. from Cincinnati, Ohio; and charging that it was misbranded in that it was a laxative and its labeling failed to warn that a laxative should not be taken in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and that frequent or continued use of a laxative might result in dependence upon laxatives to move the bowels.

On June 4, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**764. Misbranding of Pond's Digestans and Pond's Laxative Pills. U. S. v. 12 Dozen, 4 Dozen, and 1 Dozen Tins of Pond's Digestans. Default decree of condemnation and destruction. (F. D. C. No. 6538. Sample No. 74170-E.)**

The labeling of these products failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users, and did bear false and misleading therapeutic claims. The labeling also failed to state the common or usual names of the active ingredients of the laxative pills.

On December 19, 1941, the United States attorney for the District of New Jersey filed a libel against 12 dozen 15-cent, 4 dozen 35-cent, and 1 dozen 65-cent-sized tins of Pond's Digestans, each tin containing a number of brown-coated tablets and a small envelope containing 3 pink pills, labeled "Pond's Laxative Pills," at Newark, N. J., alleging that the articles had been shipped in interstate commerce on or about October 8 and November 13, 1941, by Pond Pharmacal Co., Inc., from New York, N. Y.; and charging that they were misbranded.

Analyses of samples showed that Pond's Digestans tablets consisted essentially of sodium bicarbonate, extracts of laxative plant drugs (including aloin), peppermint oil, and strychnine sulfate; and that the laxative pills consisted essentially of laxative plant drugs (including aloin and podophyllin), and small quantities of belladonna.

The articles were alleged to be misbranded: (1) In that the directions for use appearing on the tins and in the circulars were inappropriate and inadequate for a laxative since they provided for continued administration, which might result in dependence upon a laxative. (2) In that although the labeling cautioned the user against the use of laxatives in the presence of nausea, vomiting, and abdominal pain, it failed to warn that such symptoms may be those of appendicitis; and the tablets contained strychnine but the labeling failed to warn that not more than the recommended dosage should be taken and that its use by children and elderly persons might be especially dangerous. (3) In that the warnings required by law had not been placed upon the labeling with such conspicuousness as compared with other words and statements as to render them likely to be read or understood by the ordinary individual under customary conditions of purchase and use since the warning that did appear was in very small type and at the bottom of the first page of the circular enclosed in the tin. (4) In that the following statements in the labeling, "Digestans \* \* \* These tablets \* \* \* have been found of great value \* \* \* in relieving \* \* \* wind colic. \* \* \* contain bitter stomach tonics used to stimulate the flow of gastric juices. \* \* \* Oil of Peppermint is \* \* \* stimulant to the appetite \* \* \* Gentian is a stimulant to the appetite and is the most popular of all the bitters for its stomachic action. Ipecac in small doses is a carminative, stimulates the appetite and helps the action of the other ingredients. \* \* \* Rhubarb is also a widely prescribed remedy as a \* \* \* bitter," were false and misleading since the name "Digestans" created the impression